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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

MSDI-77/PC753.00

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on January 28, 2009

Signature

Typed or printed

name Douglas A. Collier

Application Number

10/648,056

Filed

August 26, 2003

First Named Inventor

Jeff R. Justis et al.

Art Unit

3774

Examiner

Alvin J. Stewart

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒

attorney or agent of record.

Registration number 43,556☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

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January 28, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.☐

\*Total of \_\_\_\_\_ forms are submitted.

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#1941129

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent	)	
application of:	)	Before the Examiner:
Jeff R. Justis, et al.	)	Alvin J. Stewart
	)	
Serial No. 10/648,056	)	Group Art Unit:
	)	3774
Filed: August 26, 2003	)	
	)	January 28, 2009
SYSTEMS AND METHODS FOR	)	
INTERVERTEBRAL REDUCTION	)	Atty Docket No.
	)	MSDI-77/PC753.00

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In response to the Final Office Action mailed July 29, 2008, and Advisory Action mailed November 26, 2008, please consider the following Pre-Appeal Brief Request for Review along with a Notice of Appeal, and form PTO/SB/33 Pre-Appeal Brief Request for Review is submitted herewith along with the fee under 37 CFR 41.20(b)(1). Since a Response to the Final Office Action was filed September 29, 2008 within two months of the mailing date of the Final Office Action, and the Advisory Action was mailed after the three month response deadline of October 29, 2008, extensions of time are measured from the mailing date of the Advisory Action, and therefore a three month extension of time to and including January 26, 2009, is submitted herewith along with the fee for the same. Please provide any additional extensions of time necessary and charge any additional fees due, or credit any overpayment, to Deposit Account 12-2424, but not including the payment if issue fees.

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

January 28, 2009  
Date of Transmission

Douglas A. Collier  
Name of Registered Representative

Douglas A. Collier  
Signature

January 28, 2009  
Date of Signature

### **REMARKS**

In the Final Office Action mailed July 29, 2008, and Advisory Action mailed November 26, 2008, claims 1-14, 44-64, 67 and 69 were pending and claims 2-4, 8-10, 48-50 and 58-60 were withdrawn. Claims 1, 5-7, 11-14, 44-47, 51-57, 61-64, 67 and 69 stand finally rejected. It is respectfully submitted that a prima facie case for rejecting these claims has not been established.

Claims 1, 5, 7, 11-14, 44, 45, 47, 51-56 and 60-69 were indicated to be rejected under 35 USC § 103(a) as unpatentable over U.S. Patent No. 5,755,797 to Baumgartner in view of U.S. Patent No. 6,620,196 to Trieu. Arguments for the patentability of the currently pending independent claims 1, 44, and 55 can be found from p. 2, 2<sup>nd</sup> para. thru the 2<sup>nd</sup> full para. on p. 6 in Applicant's 9/29/08 response to the 7/29/08 Final Office Action; from p. 8, 3<sup>rd</sup> para. thru the 1<sup>st</sup> full para. on p. 13 in Applicant's 4/22/08 response to the 1/22/08 Non-final Office Action; from p. 10, 2<sup>nd</sup> full para. thru the last para. beginning on p. 12 in Applicant's 10/31/07 preliminary amendment submitted with an RCE in which claims 1, 44 and 55 were amended to their currently pending form in response to the 9/28/07 Final Office Action.

It is respectfully submitted that the outer shell in Trieu is not able to rigidly fix the support members 7 of Baumgartner at the volume of the intervertebral space occupied by support members 7. The Examiner states that the outer shell in Trieu provides flexibility to the implant, and Baumgartner teaches support members 7 that are elastic and that elastically deform under stress from the loading of the spinal column. In contrast, Applicants' invention in claim 1 includes "means for rigidly fixing said plurality of reductions element at said volume in engagement with one another". Claim 1 also recites that the reductions elements are "selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture....." Since the reduction elements in claim 1 are rigidly fixed at the volume occupied by the reduction elements in the intravertebral space, post-operative maintenance of the reduction of the vertebral body is achieved since the volume is rigidly fixed. In contrast, the support members 7 of Baumgartner, which deform under stress from spinal column loading. and the flexible outer shell of Trieu, which permits deformation of support members 7 under stress, would not rigidly fix the support members 7 at the volume occupied by support members 7 in the disc space. Rather, the volume occupied by the support members 7 of Baumgartner is not rigidly fixed but varies in

response to the stress from spinal column loading. Trieu does not remedy the deficiencies of Baumgartner since shell 10 is also elastic and flexible, and does not function to provide “means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body” as recited in claim 1.

Furthermore, while support members 7 in Baumgartner occupy a volume in the disc space, this volume occupied by support members 7 is not rigidly fixed by the elastic and flexible shell in Trieu since Baumgartner teaches support members 7 elastically deform under stress and Trieu teaches a flexible and elastic shell that also deforms. When deformed under stress, the support members 7 occupy a different volume than when not deformed, and the volume occupied by support members 7 thus is not rigidly fixed.

Since claim 1 recites, among other features, “wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and means for rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body...” (emphasis added), the combination of Baumgartner and Trieu does not support a prima facie case for rejecting claim 1.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claims 44 and 55. Claim 44 recites “a plurality of reduction elements positionable in an intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements act randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space compressing cancellous bony tissue and applying an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said plurality of reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another.”

As discussed above with respect to claim 1, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume occupied by the support members 7 in the spinal disc space. Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae. Furthermore, the volume occupied by support members 7 is not rigidly fixed since Baumgartner further teaches that “during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus.” See col. 1, line 62-65. The Examiner fails to identify any teaching or disclosure in Baumgartner that support members 7 have a rigidly fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents rigidly fixing the volume occupied by support members 7 of Baumgartner.

Furthermore, even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 of Baumgartner at a volume occupied by the support members 7 in the spinal disc space. There is no teaching that outer shell 30 rigidly fixes the volume of elastic body 15, or that outer shell 30 would rigidly fix the volume of the elastic support member 7 of Baumgartner. Therefore, a prima facie case for rejecting claim 44 has not been established.

The combination of Baumgartner and Trieu also fails to teach or suggest all the elements in claim 55. Claim 55 recites “plurality of reduction elements positionable in an intravertebral space adjacent one another in contact with bony tissue, wherein said plurality of reduction elements include exterior surface means for facilitating engagement between adjacent reduction elements and for facilitating said reduction elements acting randomly and radially one upon the other upon sequential positioning thereof in the intravertebral space to compress cancellous bony tissue and apply an outwardly directed corrective force in the vertebral body, wherein said plurality of reduction elements are selected in number to occupy a volume within the intravertebral space that reduces a vertebral fracture and restores the vertebral body; voids between respective ones of said reduction elements; and material filling said voids and rigidly fixing said plurality of reduction elements at said volume in engagement with one another in the intravertebral space for post-operative maintenance of the reduction of the vertebral body, said material locking said plurality of reduction elements relative to one another.”

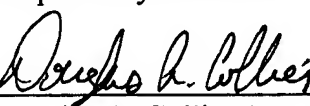
As discussed above with respect to claims 1 and 44, neither Baumgartner nor Trieu teach any material filling voids to rigidly fix support members 7 at a volume occupied by the support members in the spinal disc space. Rather, support members 7 are selected in number to replace a core region of an intervertebral disk (3) and to elastically support the vertebrae. The volume occupied by support members 7 is not rigidly fixed since Baumgartner teaches that “during loading, the support members are elastically deformed, and the compressive forces acting in the direction of the member axis are converted into edges stresses in the annulus fibrosus.” *See* col. 1, line 62-65. The Examiner fails to identify any teaching or disclosure in Baumgartner that support members 7 have a rigidly fixed volume and these structural features in claim 1 cannot be read on Baumgartner since the compression of the elastic support members 7 prevents rigidly fixing the volume occupied by support members 7.

Even if outer shell 30 in Trieu were placed around support members 7, outer shell 30 is not taught to rigidly fix support members 7 at a volume occupied by the support members in the spinal disc space. There is no teaching that outer shell 30 rigidly fixes the volume of elastic body 15, or that outer shell 30 would rigidly fix the volume of the elastic support member 7 of Baumgartner. T

Claims 5-7, 11-14, 45-47, 51-54, 56-57, and 61-64, 67, and 69 depending from claims 1, 44 and 55 are allowable at least since the claim from which each depends is allowable and for other reasons provided in applicants previous responses. See, for example, Applicant’s 4/22/08 response from the 3<sup>rd</sup> full para. on page 13 to the 1<sup>st</sup> full para. on p. 14, and also Applicant’s 10/31/07 and 7/13/07 response on 1<sup>st</sup> full para. of page 13.

Reconsideration and allowance of the present application including claims 1-14, 44-64, 67, and 69 is respectfully requested.

Respectfully submitted

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